UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,858	08/20/2001	Friedrich Altmann		5615

7590 04/30/2004

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria, VA 22313-1404

EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,858	ALTMANN, FRIEDRICH	
	Examiner	Art Unit	
	Sean R McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-58 and 60-119* is/are pending in the application.

4a) Of the above claim(s) *35-48,53-56,64-75,78-82 and 87-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-52,57,58,60-63,76,77,83,84 and 108-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/01, 1/02, 2/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group II, in Papers filed 12/18/02 (copy faxed 1/28/03) is acknowledged. The traversal is on the ground(s) that unity of invention exists in the instant case since all the inventions are linked via being a DNA homologous or complementary to SEQ ID NO: 1. First, this is not correct since the claims in the instant group are drawn to the use of a DNA of reverse orientation of SEQ ID NO: 1 which produces and antisense transcript and further is drawn to Ribozymes targeted to mRNA and are therefor different categories of inventions where unity of invention of different categories of invention are set forth in 37 CFR 1.475 which is set forth below. It is clear from a reading of 37 CFR 1.475 that the restriction is proper. Applicant also argues that the art cited does not teach a sequence that a plant protein with specific properties, however it is noted that those sequences contain all the structural limitations required in the instant Claim 35, for example, and without evidence to the contrary are assumed to have such properties since the Office cannot make such a determination without the facilities to make such a determination, for example.

The requirement is still deemed proper and is therefore made FINAL.

However, claims 57, 58, 60 and claims 108-119 will be examined since they are drawn to the same invention of Group II as applicant argues at the paragraph bridging pages 8 and 9 of the election. Claims 64, 65, 78, 79, 85 and 86 were clearly improperly included in group II as it is clear that they are not drawn to antisense or ribozymes and should have been included in Group III as claim 61 from which these claims depend is

included properly in Group III. Claims 49-52, 57, 58, 60-63, 76, 77, 83, 84 and 108-119 are therefore under examination.

Claims 35-48, 53-56, 64-75, 78-82 and 87-107 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Papers filed 1/28/03.

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention "). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features " shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Claims 49-52, 57, 58, 60-63, 76, 77, 83, 84, and 108-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claims all ultimately depend from withdrawn claim 35. Since claim 35 has been withdrawn from consideration the metes and bounds of the instant claims are unclear.

Claims 49 and 50 both recite "the promoter", there is no antecedent basis for this limitation in the claims.

If applicant corrects the deficiencies (in regard to dependency on withdrawn claim) above the following rejection would apply to claims 49-52, 57, 58, 60-63, 76, 77, 83, 84, and 108-119.

The claims would be rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO: 1, which corresponds to the cDNA encoding the mung bean species of α1, 3-fucosyl transferase. SEQ ID NO: 1 meets the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to encompass methods that use, cells that contain and vectors that contain

sequences that are, sequences that hybridize to SEQ ID NO: 1, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. The specification discloses only one example of a plant sequence (Mung bean) and provides no basis for what the structure of other plant α1, 3-fucosyl transferase sequences would be. It is stated, for example, at page 3, that the specificity of the enzyme from human cells is quite different than that of plant cells, for example. The instant invention relies of the broad range of potential and undescribed sequences to construct antisense expression vectors, cells containing such, vectors expressing ribozymes that may cleave undescribed V mRNA. The claims require that the vectors and cells which contain.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written

description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only those invention drawn to SEQ ID NO: 1 but not the full breadth of the claims (or none of the sequences encompassed by the claim) meets the written

description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The invention is drawn to vectors that contain a DNA of Claim 35 which is inversely orientated with respect to a promoter (claims 49, 50). This vector produces an antisense transcript of the DNA claimed in claim 35 which antisense is intended to inhibit a GlcNAc-α1, 3-fucosyl transferase in cells that contain such a vector (claims 57, 58, 108-119), a DNA molecule encoding a ribozyme targeting a plant α1, 3-fucosyl transferase nucleic acid as defined in claim 35 (claims 51 and 52) which inhibit a plant α1, 3-fucosyl transferase in cells (claims 62, 63, 76, 77, 83,and 84). The construction of the antisense and ribozyme expression vectors for use in the claimed invention require a description of the specific plant α1, 3-fucosyl transferase sequences targeted. As has been set forth above, only one such sequence, SEQ ID NO: 1, has been described in the instant specification. The instant specification does not provide any specific ribozyme sequences or antisense sequences other than those that are completely complimentary to a target nucleic acid sequence based on SEQ ID NO: 1, for example. The specification fails to provide any specific structure such that one in the art would know what structures would be required for the specific inhibition of any of a wide scope of plant α1, 3-fucosyl transferase nucleic acid targets embraced within the instant claims. No specific structure function relationship has been established in the specification or in the prior art for the antisense and ribozyme sequences for use in the

instant invention,. The specification also fails to provide an adequate description in figures or words since there is no disclosure of the structures of the target nucleic acids let alone the structures of the antisense and ribozyme sequences instantly claimed, for example.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRM

SEAN McGARRY
PRIMARY EXAMINER
1635